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09/554,793	09/19/2000	Volker Zimmer	RDID0043US	1444

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THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.
JILL L. WOODBURN
128 SHORE DR.
OGDEN DUNES, IN 46368

EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,793

Applicant(s)

ZIMMER, VOLKER

Examiner

Elizabeth Quan

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,7 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 9/9/2002 has been acknowledged. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: It appears DETAILED DESCRIPTION OF THE DRAWINGS should be inserted before the last paragraph on page 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 2-5, 9-14, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,997,817 to Crismore et al.

Referring to claims 2-5, 9-14, and 16, Crismore et al. disclose a device for withdrawing liquid samples for analytical elements (see ABSTRACT). The device

Art Unit: 1743

comprises a carrier (1) and cover (7) (see FIGS. 1, 2, and 3i). The cover (7) has a surface (9) that cooperates with a surface (22) of the carrier (1) to form a capillary-active channel as defined by a second surface (17) of second cover (13), edges of a first notch (11) on cover (7), first surface (22) of carrier (1), and conductive tracks (5,6) (see FIGS. 1, 2, and 3i; COL. 2, lines 62-64; COL. 3, lines 58-61; COL. 4, lines 42-48). The channel has a sample application opening near indentation (2), second notch (3), and vent hole (4) on the exposed part of the surface (22) of carrier (1), which is directly underneath the first notch (11) (see FIGS. 1, 2, and 3i; COL. 3, lines 1 and 2; COL. 4, lines 1-11 and 13-23; COL. 5, lines 15-25 and 36-59). The first notch (11) is in the form of a partial groove or depression, which is located in the cover (7), that forms the channel at an edge of the sample application opening so that one side of the edge of the sample application opening is interrupted by the first notch (11) and the surface (22) facing the channel opposite to the first notch (11) is exposed (see FIGS. 1, 2, and 3i). The first notch (11), second notch (3), and third notch (15) are essentially located next to one another in different layers (see FIGS. 1, 2, and 3i). Vent hole (4) in the form of a notch is staggered relative to the first, second, and third notches (11,3,15) (see FIGS. 1, 2, and 3i). An intermediate layer as defined by conductive tracks (5,6) or dried test reagent (12) or hydrophilic coating (25) is positioned between a second cover (13) and carrier (1) (see FIGS. 1, 2, and 3i; COL. 5, lines 1 and 2; COL. 8, lines 37-51). When the edge of the sample application opening adjacent to the notch is contacted with a liquid sample, the sample is transported by capillary forces into the channel (see FIGS. 1, 2, and 3i; COL. 2, lines 5 and 6; COL. 8, lines 55-59; COL. 9, lines 42 and 43). The hydrophilic coating (25) is placed against a

Art Unit: 1743

surface (17) of the second cover (13) directly over the dried test reagent (12) on carrier (1) in the exposed surface opposite to the notch, which takes part in forming the boundaries of the capillary channel, to impart a hydrophilic nature to the internal surface of the capillary channel to urge the flow of a sample into the channel (see FIGS. 1, 2, and 3i; COL. 8, lines 37-51). Therefore, Crismore et al. includes all the limitations in claims 2-5, 9-14, and 16.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 5, 9-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al. in view of GB 2 090 659 A to Kelley et al.

Referring to claims 4, 5, 9-14, and 16, Sugarman et al. disclose a liquid diagnostic device with the leading edge (11) of the liquid shield (10) projecting upward from a substantially flat upper surface (21) of the cartridge (20) (see FIGS. 1-5; COL. 3, lines

Art Unit: 1743

15-18). A portion (14) of the shield (10) is attached at an edge of the liquid receiving well (22) (see FIGS. 1-5; COL. 4, lines 23-25). Shield (10), which is the surface facing the capillary path opposite to the notch, is exposed (see FIGS. 1-3). While the shield (10) is primarily for confining sample liquid in the receiving well (22), the shield (10) may fulfill the auxiliary function of blocking light from reaching the surface (31) of the monitor and/or the gap (32) between the cartridge surface (21) and monitor surface (31) (see COL. 3, lines 40-45; COL. 4, lines 50-60). The well is a notch in the form of a groove or depression on the cartridge surface (21) at the edge of the sample application opening as defined by the boundaries of the portion (14) of shield (10) and the outer edges of the cartridge (20) (see FIGS. 1, 3, and 4). When one or two drops of blood are applied to the well (22) in the cartridge (20), the liquid automatically flows into a chamber containing reagent and continues traveling through a capillary path until the blood coagulates (see FIGS. 1-5; COL. 2, lines 61-67). Since the capillary path is automatically filled with blood, it appears that at least one of the surfaces forming the inner surface of the capillary path and the exposed surface opposite to the notch are hydrophilized.

Sugarman et al. do not explicitly disclose the surfaces of the cover and carrier cooperating to form a capillary-active channel. Kelley et al. provide the limitation of the surfaces of the cover and carrier cooperating to form a capillary active channel.

Kelley et al. disclose a device for withdrawing samples of liquid for analytical elements (see ABSTRACT). The device comprises a carrier (48) and cover (10) (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 36-125). The cover (10) has a surface (18)

Art Unit: 1743

that cooperates with a surface of the carrier (48) to form a capillary-active channel (16), which has a sample application opening (12) (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 36-125). At least one notch in the form of a partial groove is located in one of the carrier (48) and cover (10) surfaces forming the channel (16) at an edge of the sample application opening (12) of the channel (16) such that one side of the edge of the sample application opening (12) is at least partially interrupted by the at least one notch (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 36-125). An intermediate layer (42) is positioned between the second cover (46) and carrier (48) (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 36-125). When the edge of the sample application opening (12) adjacent to the notch is contacted with a liquid sample, the sample is transported by capillary forces into the channel (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 96-104). Since channel (16) is typically filled with blood within less than four seconds with the edge of the opening (12) touching the drop of block, it appears that at least one of the surfaces forming the inner surface of the channel (16) and the exposed surface opposite to the notch are hydrophilized (see FIGS. 1-5; SPECIFICATION: PAGE 2, lines 101-104).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sugarman et al. to have surfaces of the cover and carrier cooperating to form a capillary-active channel as in Kelley et al. to enable accurate metering and positioning of a sample to be analyzed efficiently and distributing the sample uniformly in the metering area for exposure to reagent material.

Art Unit: 1743

8. Claims 2, 9 (alternative), and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al. and GB 2 090 659 A to Kelley et al. in view of U.S. Patent No. 5,997,817 to Crismore et al.

Referring to claims 2, 9 (alternative), and 16, neither Sugarman et al. nor Kelley et al. show notches resembling the instant invention. However, Crismore et al. show notches that resemble the instant invention (see FIGS. 1 and 2). Crismore et al. disclose that the notch reduces dose hesitation (see ABSTRACT; COL. 2, lines 15-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sugarman et al. in view of Kelley et al. to provide notches that resemble the instant invention as in Crismore et al. to reduce dose hesitation.

9. Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al. and GB 2 090 659 A to Kelley et al. and optionally U.S. Patent No. 5,997,817 to Crismore et al. in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claims 7 and 15, Sugarman et al. in view of Kelley et al. and optionally Crismore et al. do not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane

Art Unit: 1743

(APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the device of Sugarman et al. in view of Kelley et al. and optionally Crismore et al. to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

10. Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,997,817 to Crismore et al. in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claims 7 and 15, Crismore et al. do not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-19, 38, and 39). APS provides a high level of functionalization in terms of surface

Art Unit: 1743

binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the device of Crismore et al. to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al. and GB 2 090 659 A to Kelley et al. and optionally U.S. Patent No. 5,997,817 to Crismore et al. in view of U.S. Patent No. 4,254,083 to Columbus.

Referring to claim 3, Sugarman et al. in view of Kelley et al. and optionally Crismore et al. do not show or disclose staggered notches. However, Columbus shows notch (30) for sample application and notch (80) for viewing the transport of the sample within the device. The notches appear to be staggered to provide desired views of the device, such as the portion of the channel downstream of the sample application opening (see FIG. 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sugarman et al. in view of Kelley and optionally Crismore et al. to provide staggered notches for the sample application opening and viewing window as in Columbus to provide desired views of the channel downstream from the sample application opening.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,997,817 to Crismore et al. in view of U.S. Patent No. 4,254,083 to Columbus.

Referring to claim 3, Crismore et al. do not show or disclose staggered notches. However, Columbus shows notch (30) for sample application and notch (80) for viewing

Art Unit: 1743

the transport of the sample within the device. The notches appear to be staggered to provide desired views of the device, such as the portion of the channel downstream of the sample application opening (see FIG. 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Crismore et al. to provide staggered notches for the sample application opening and viewing window as in Columbus to provide desired views of the channel downstream from the sample application opening.

Response to Arguments

13. Examiner appreciates the amendments and responses to the first Office Action.

However, they have raised new issues.

14. Applicant's arguments with respect to claims 2-5, 7, and 9-16 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed 9/9/2002 have been fully considered but they are not persuasive.

Applicant submits that Sugarman et al. fails to disclose or suggest at least one notch in the form of a partial groove at an edge of the a sample application opening. According to Merriam-Webster's Collegiate Dictionary, a notch may be an indentation and a groove may be a depression or channel. The terminology "notch in the form of a partial groove" is broad. In Sugarman et al. the well is a notch or indentation in the form of a groove or depression on the cartridge surface (21) at the edge of the sample application opening as defined by the boundaries of the portion (14) of shield (10) and the outer edges of the cartridge (20) (see FIGS. 1, 3, and 4).

Art Unit: 1743

Applicant submits that Sugarman et al. is silent regarding a surface facing the channel opposite to the at least one notch is exposed. Sugarman et al. disclose a liquid diagnostic device with the leading edge (11) of the liquid shield (10) projecting upward from a substantially flat upper surface (21) of the cartridge (20) (see FIGS. 1-5; COL. 3, lines 15-18). A portion (14) of the shield (10) is attached at an edge of the liquid receiving well (22) (see FIGS. 1-5; COL. 4, lines 23-25). Shield (10), which is the surface facing the capillary path opposite to the notch, is exposed (see FIGS. 1-3).

Applicant submits that Sugarman et al. fails to disclose or suggest a device that comprises "a carrier and cover having a surface that cooperates..." as revealed on page 5 of the response. Examiner would like to indicate that this is an amendment to the original claim; therefore, Examiner has applied new references in this office action for the newly amended claims, which are part of the response.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1743

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq
November 26, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700